BARDA Today & Tomorrow: Goals, Priorities, Successes & Challenges

BARDA Industry Day
October 14, 2015

Dr. Robin Robinson
BARDA Director
ASPR Deputy Assistant Secretary
Some Threats Are Very Large: Pandemic Influenza

1918: “Spanish Flu”
A(H1N1)
20-100 m deaths
~500,000 in US

1957: “Asian Flu”
A(H2N2)
1-4 m deaths
60-80,000 in US

1968: “Hong Kong Flu”
A(H3N2)
1-4 m deaths
~30,000 in US

1976 Swine Flu – The “No-Show Pandemic”

2009 H1N1 Pandemic

Other Threats Are Ominous: High Pathogenic Avian Influenza Viruses

1998 - present

2013
Some Threats Emerge
Re-emerging Infectious Diseases

SARS-CoV
2003-2004

MERS-CoV
2012-2015
Some Threats May Be Man-Made

- Radiological and Nuclear agents
- *Bacillus anthracis* (anthrax)
- *Bacillus anthracis* – Multi-drug resistant (MDR anthrax)
- Botulinum toxins (botulism)
- Variola virus (smallpox)
- *Yersinia pestis* (plague)
- *Franciscella tularensis* (tularemia)
- Hemorrhagic Fever Viruses - Ebola, Marburg
- *Burkholderia mallei* (glanders)
- *Burkholderia pseudomallei* (melioidosis)
- *Rickettsia prowazekii* (typhus)
- Low volatility and volatile nerve agents
- Hydrogen, potassium, and sodium cyanide
Ebola is both a biothreat and an emerging infectious disease
Threat-Based
Preparedness & Response
Resilience Chain

Detection and Diagnosis
Medical Countermeasures
Treating and Isolating Sick
Environmental Cleanup
Actionable Information
Countermeasure Dispensing
Protecting the Well
Medical Countermeasures
Medical Countermeasures

Medical Devices  Antimicrobials  Diagnostics  Vaccines  Therapeutics
Vaccine & Drug Development is still Expensive, Risky and Lengthy

**PHASES**
- Discovery
- Preclinical Development
  - IND
- Phase I
- Phase II
- Phase III
- Licensure
- Production & Delivery

**PRODUCT PIPELINE**

- NIH & DoD
- Project BioShield ($5.6B)
- NIH ($11.8B)
- BARDA ($540M)
- BARDA ARD
- NIH & DoD

**PROBABILITY OF SUCCESS TO LICENSURE**

- 1-3%
- 5-17%
- 10-25%
- 18-35%
- 45-70%
- 90%

**TIME**

- 3-7 yr
- 0.5-2 yr
- 1-2 yr
- 2-3.5 yr
- 2.5-4 yr
- 1-2 yrs

**PIPECLINE PHASE COST**

- $100M -130M
- $60-70M
- $70M-100M
- $130M-160M
- $190M-220M
- $18M-20M

**EBOLA MCMs**
- 2014-2015

**MERS-COV MCMs**
- 2012-2015

**Valley of Death**

Public Health Emergency Medical Countermeasure Enterprise

(PHEMCE)

Governance Process
Biodefense MCM History

- Pandemic & All-Hazards Preparedness Act (2006)
- Medical Countermeasure Review (2010)
- Pandemic & All-Hazards Preparedness Reauthorization Act (2013)
- PHEMCE Strategic & Implementation Plan (2014)

Mid-1950’s on: DoD bio and chem defense programs
9/11 terrorist attacks and anthrax letters

1990-1992
1st Gulf War founded
Iraqi BW, CW & nuke programs

1999
NPS “Animal Rule” (May 2002)

2002
National Strategy for Pandemic Influenza (Nov 2005)

2004
Project BioShield (Jul 2004)

2005
PREP Act (Dec 2005)
PAHPA (Dec 2006) → BARDA (Apr 2007)

2009-2010

2013
PAHPRA

2014
PHEMCE SIP
Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Governance

ASPR/NIH BARDA BARDA CDC/SNS CDC/SNS BARDA CDC and ASPR/OEM CDC ASPR

FDA

Requirements R & D Advanced Development Acquisition & Stockpiling Storage/Maintenance Deployment Evaluation

PHEMCE COORDINATED PLANNING & EXECUTION

Other Members:


PHEMCE CBRN Medical Countermeasure Process

DHS

Pillar 1
Identify and Assess Threats

BARDA

Pillar 2
Evaluate Medical and Public Health Consequences

ASPR/OPP

Pillar 3
Establish Medical Countermeasure Requirements

NIH
BARDA CDC

Pillar 4
Implement SIP for MCM Development & Acquisition
BARDA MCM Story
BARDA’s Mission

Support advanced development of and make available medical countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by transitioning MCM candidates from early development across the “Valley of Death“ into advanced development to regulatory approval.

O’Neil Building, Washington, DC

BARDA Strategic Goals 2011 -2016

- **Goal 1:** An advanced development pipeline replete with medical countermeasures and platforms to address unmet public health needs, emphasizing innovation, flexibility, multipurpose and broad spectrum application, and long-term sustainability
- **Goal 2:** A capability base to provide enabling core services to medical countermeasure innovators
- **Goal 3:** Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats
- **Goal 4:** Responsive and nimble programs and capabilities to address novel and emerging threats
- **Goal 5:** A ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies
BARDA Key Element #1: Create Robust & Innovative MCM Development Pipeline

- ~ 200 MCM product candidates in development
BARDA Key Element #2: Stockpile CBRN MCMs under Project BioShield

Smallpox

Radiation

Thermal Burns 2015

Chemical

Anthrax

Botulism

BARDA Success Key #3: Seek FDA Approval

Cell-based Influenza Vaccine
- FLUCELVAX
- Influenza Virus Vaccine
- Novartis

Recombinant-based Influenza Vaccine
- Protein Sciences Corp.

Influenza IV Antiviral Drug
- BioCryst Pharmaceuticals, Inc.

H1N1 & H5N1 Vaccines w/ Adjuvant
- GlaxoSmithKline

Botulinum Antitoxin
- HGS/GSK

Next-Generation Portable Ventilators
- Covidian

Flu/RSV POC Diagnostic
- 3M/Focus

ANTHRAX ANTITOXINS
- Emergent

Amgen

BARDA Key Element #5: Establish Robust Manufacturing Capacity

• Expanding Existing Capacity by Retrofitting Vaccine Manufacturing Infrastructure

sanofi pasteur – Swiftwater, PA

• New Vaccine Mfg. Facilities

Novartis – Holly Springs, NC

2013 ISPE Facility of the Year
BARDA Key Element #6: Help MCM Developers for Preparedness & Response

BARDA Key Element #7: Have the Best Technical, Clinical, & Regulatory Staff
BARDA State of Affairs
BARDA 2015: Harvesting ARD Bounty for PBS & Moving the Frontiers of Influenza MCMs

• Development pipeline
  — Ebola Response – 12 MCMs & Natl. MCM Response Infrastructure
  — CARB launch preparations
  — More effective influenza vaccines with universal potential
  — 1st influenza immunotherapeutic development project started
  — Ebola epidemic winding down! Impacts on Vax & Rx efficacy studies

• Stockpiling
  — PBS – 4 new thermal burn treatments & more MCMs on budget hold

• FDA approval
  — FDA approval of Rapivab, Neupogen, AlG, Fluad, & Cobas

• Partnerships
  — Partnered with FDA/CDER on Continuous Mfg. initiative - 1st project

• Manufacturing Expansion – International Flu Vax Mfg. Infrastructure

• Core Services Assistance programs
  — 1st projects started in BARDA’s CIADM, FFMN, & CSN

• BARDA organization – new Division leaders & Life Cycle Mgmnt.

• Antigenic drift & seasonal flu vaccine mismatch → HHS Action Plan
BARDA 2016 Strategic Goals & Expectations: Expanding Horizons Amidst Uncertainties

- Development pipeline
  - Formal launch CARB Action Plan for AMR Rx & Dx development
  - Launch MERS-CoV therapeutics program

- Stockpiling
  - Add new & enhanced MCMs under PBS

- FDA approval
  - Submit 1st IND as sponsor (H5N1 vax study)
  - Expect 2-3 FDA approved MCMs

- Partnerships
  - Establish clinical study infrastructure with Saudi Arabia for MERS-CoV MCMs

- Core Services Assistance programs
  - Expansion of CIADM capabilities with rapid platform technologies
  - Open BARDA’s new Innovation Hub for modeling

- BARDA organization
  - Prepare new BARDA Strategic Plan 2017-2022
  - Build permanent home for BARDA EID program

- Bioterrorism fatigue, disbelief, & denial → less funding?
- Global biopreparedness → IOM & WHO consultations → BARDA’s role
BARDA is Always Open

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BARDA - URL: http://www.phe.gov
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• Upcoming Events
• PHEMCE Strategy and Implementation Plan
• CBRN and Pan Flu Programs
• Business Toolkit - www.phe.gov/amcg

MedicalCountermeasures.gov

• Tech Watch program
• Federally-sponsored conferences
• Funding opportunities
• Resources core service programs
• Regulatory guidance
• Federal strategies and reports